



TUBERCULOSIS INFORMATION

Respiratory Protection

CDC Recommendations for Respiratory Protection

The following recommendations are taken from the Centers for Disease Control and Prevention (CDC) Guidelines for Preventing the Transmission of *M. tuberculosis* in Health Care Facilities, 1994. The revised guidelines are available in the *Federal Register* and in the *Morbidity and Mortality Weekly Report* (MMWR); to order copies, call (404) 639-1819.

A. Considerations for Selection of Respirators

Personal respiratory protection should be used by (1) persons entering rooms where patients with known or suspected infectious TB are being isolated, (2) persons present when cough-inducing or aerosol-generating procedures are performed on such patients, and (3) persons in other settings where administrative and engineering controls are not likely to protect them from inhaling infectious airborne droplet nuclei. These other settings should be identified on the basis of the facility's risk assessment.

Although data regarding the effectiveness of respiratory protection from many hazardous airborne materials have been collected, the precise level of effectiveness in protecting health care workers (HCWs) from *M. tuberculosis* transmission in health care settings has not been determined. Information concerning the transmission of *M. tuberculosis* is incomplete. Neither the smallest infectious dose of *M. tuberculosis* nor the highest level of exposure to *M. tuberculosis* at which transmission will not occur has been defined conclusively. Furthermore, the size distribution of droplet nuclei and the number of particles containing viable *M. tuberculosis* that are expelled by infectious TB patients have not been defined adequately, and accurate methods of measuring the concentration of infectious droplet nuclei in a room have not been developed.

Nevertheless, there is evidence that administrative and engineering controls may not adequately protect HCWs from airborne droplet nuclei in certain settings (e.g., TB isolation rooms, treatment rooms in which cough-inducing or aerosol-generating procedures are performed, and ambulances during the transport of infectious TB patients). Respiratory protection devices used in these settings should have characteristics that are suitable for the organism they are protecting against and the settings they are used in.

B. Performance Criteria for Personal Respirators

Respiratory protective devices used in health care settings for protection against *M. tuberculosis* should meet the following standard performance criteria:

1. The ability to filter particles 1 micrometer in size in the unloaded state with a filter efficiency of 95% or greater (i.e., filter leakage of 5% or less), given flow rates of up to 50 L per minute. (Available data suggest that infectious droplet nuclei range in size from 1 micrometer to 5 micrometer; therefore, respirators used in health care settings

should be able to efficiently filter the smallest particles in this range. Fifty liters per minute is a reasonable estimate of the highest airflow rate an HCW is likely to achieve during breathing, even while performing strenuous work activities.)

2. The ability to be qualitatively or quantitatively fit tested in a reliable way to obtain a face-seal leakage of 10% or less.
3. The ability to fit the different facial sizes and characteristics of HCWs, which can usually be met by making the respirators available in at least three sizes.
4. The ability for HCWs to be checked for facepiece fit, in accordance with Occupational Safety and Health Administration (OSHA) standards and good industrial hygiene practice, each time they put on their respirators.

These criteria are based on currently available information, including (1) data on the effectiveness of respiratory protection against noninfectious hazardous materials in workplaces other than health care settings and on interpretation of how these data can be applied to respiratory protection against *M. tuberculosis*; (2) data on the efficiency of respirator filters in filtering biological aerosols; (3) data on face-seal leakage; and (4) data on the characteristics of respirators that were used in conjunction with administrative and engineering controls in outbreak settings where transmission to HCWs and patients was terminated.

In some settings, HCWs may be at risk for two types of exposure: (1) inhalation of *M. tuberculosis* and (2) mucous membrane exposure to fluids that may contain bloodborne pathogens. In these settings, protection against both types of exposure should be used. When operative procedures (or other procedures requiring a sterile field) are performed on patients who may have infectious TB, respiratory protection worn by the HCW should serve two functions:

1. It should protect the surgical field from the respiratory secretions of the HCW.
2. It should protect the HCW from infectious droplet nuclei that may be expelled by the patient or generated by the procedure.

Respirators with exhalation valves and positive-pressure respirators do not protect the sterile field; therefore, a respirator that does not have a valve and that meets the standard performance criteria should be used.

C. Reuse of Respirators

Conscientious respirator maintenance should be an integral part of an overall respirator program. This maintenance applies both to respirators with replaceable filters and respirators that are classified as disposable but that are reused. Particulate respirators can be used for as long as they remain functional. They should be discarded if the filter material is physically damaged, soiled, or fails the fit check.

D. Risk Assessment and Respiratory Protection

Facilities that do not have isolation rooms and do not perform cough-inducing procedures on patients who may have TB may not need to have a respiratory protection program for TB; this determination should be based on the facility's risk assessment. Such facilities should have written protocols for the early identification of patients who have signs or symptoms of TB and procedures for referring these patients to a facility where they can be evaluated and managed appropriately. These protocols should be evaluated regularly and revised as needed.

A facility's risk assessment may identify a limited number of situations (e.g., bronchoscopy on patients suspected of having TB or autopsy on persons suspected of having had TB at the time of death) where the estimated risk of transmission of *M. tuberculosis* justifies a higher-than-normal level of respiratory protection. In such circumstances, employers should provide HCWs who are exposed to *M. tuberculosis* a level of respiratory protection exceeding the standard criteria and compatible with patient-care delivery (e.g., negative-pressure respirators that are more protective; powered air-purifying particulate respirators [PAPRs]; or supplied-air respirators).

E. Respiratory Protection and Patients or Visitors

To reduce the expulsion of droplet nuclei into the air, patients suspected of having or known to have TB should wear surgical masks when not in TB isolation rooms. Surgical masks are designed to prevent the respiratory secretions of the person wearing the mask from entering the air. TB patients do not need to wear particulate respirators, which are designed to filter the air before it is inhaled by the wearer. TB patients should never wear a respirator with an exhalation valve; this type of respirator does not prevent expulsion of droplet nuclei into the air.

Visitors to TB patients should be given respirators to wear while in isolation rooms, and they should be given general instructions on how to use their respirators.

OSHA Respiratory Protection Standards and NIOSH Certification

Health care facilities in which respiratory protection is used to prevent inhalation of *M. tuberculosis* are required by OSHA to develop, implement, and maintain a respiratory protection program. An effective and reliable respiratory protection program must contain at least the following elements:

1. Assignment of responsibility
2. Standard operating procedures
3. Medical screening
4. Training
5. Face-seal fit testing and fit checking
6. Respirator inspection, cleaning, maintenance, and storage
7. Periodic evaluation of the personal respiratory protection program

All HCWs who use respiratory protection should be included in this program. HCWs with latex allergy should be assigned respirator facepieces that contain no latex.

The OSHA respiratory protection standard requires that all respiratory protective devices used in the

workplace be certified by the National Institute for Occupational Safety and Health (NIOSH). NIOSH-approved high efficiency particulate air (HEPA) respirators have been the only available air-purifying respirators that met or exceeded the standard performance criteria recommended by the CDC. On July 10, 1995, however, NIOSH updated its respirator testing and certification requirement to permit approval of better respirators for workers, including hospital employees caring for patients with highly infectious tuberculosis. This new requirement was developed with input from safety professionals, respirator manufacturers, representatives of health care facilities, and affected workers.

Under the new particulate filter tests, NIOSH will certify three classes of filters (N-, R-, and P-series), with three levels of filter efficiency (95%, 99%, and 99.97%) in each class. All filter tests will employ the most penetrating aerosol size: 0.3 micrometer aerodynamic mass median diameter. The R- and P-series of filters will be tested using a highly degrading aerosol of dioctylphthalate (DOP) and so are more applicable to industrial needs. The N-series filters will be tested using a mildly degrading aerosol of sodium chloride (NaCl). Tested to a specified maximum loading level (200 mg), the N-series filters will be restricted to workplaces that are free of oil or other severely degrading aerosols.

All nine categories of air-purifying particulate respirators exceed the filter performance criterion recommended by the CDC to prevent the transmission of *M. tuberculosis* in health care facilities. Respirators that contain a NIOSH-certified **N-series filter with a 95% efficiency (N-95) rating** will be appropriate for use in accordance with the CDC guidelines.

The certification of air-purifying respirators under the final rule will enable respirator users to select from a broader range of certified respirators, several of which are expected to be less expensive than respirators with HEPA filters. A few of the currently available dust-fume-mist respirators may be re-certified at the N-95 level under the new NIOSH requirement.

Further information on respirator certification may be found in the NIOSH standards, which were published on June 8 in the *Federal Register*. A technical summary and the full text of the regulation can be obtained by calling the NIOSH toll-free information number at 1 (800) 35-NIOSH (select option 5) or downloaded from the NIOSH World Wide Web page (<http://www.cdc.gov/niosh/homepage.html>).

NIOSH is a part of the Centers for Disease Control and Prevention (CDC) within the U.S. Public Health Service, Department of Health and Human Services. The CDC is not a regulatory agency, and its recommendations on infection control are not regulations. For regulations in your area, contact your state or local OSHA office. OSHA will soon be developing a new TB standard to address infection control and respiratory protection in health care settings; in the meantime, OSHA has indicated that it will incorporate the new NIOSH standards governing filter penetration.

Particulate Respirators Certified Under 42 CFR Part 84

On July 10, 1995, the new certification standard for particulate respirators went into effect. This regulation, 42 CFR Part 84, replaced the long-standing regulation 30 CFR Part 11. (Commonly referred to as Part 84 and Part 11, respectively.) The new Part 84 covers all respirator types (self-contained breathing apparatus, air-line respirators, gas and vapor respirators, powered respirators, etc.) but only the standards for nonpowered, particulate respirators have changed from the provisions of the old Part 11.

The following is a list of nonpowered, particulate respirators that have been tested and certified by NIOSH under the provisions of the new Part 84. Other respirator types certified under the provisions of Part 84 are not included in this listing. Also not included are combination particulate respirators such as particulate filters in combination with gas and vapor filters. As additional respirators are certified, they will be added to this list. Additions are made to this list in the order that they receive certification.

Note: There may be multiple entries with the same certification number when the respirator represented by that certification number is marketed by different suppliers, under private labels.

Particulate Respirators Certified Under 42 CFR Part 84

Approval Number	Supplier	Phone	Respirator Type	Trade Name	Exhalation Valve
84A-0001	Better Breathing, Inc.	1-800-638-6275	N95, Filtering facepiece	APR-3-N95-1	Yes
84A-0002	Racal Health and Safety, Inc.	1-800-682-9500	N95, Filtering facepiece	Delta N95	Yes
84A-0003	Racal Health and Safety, Inc.	1-800-682-9500	N95, Filtering facepiece	Delta N95	No
84A-0004	Racal Health and Safety, Inc.	1-800-682-9500	N100, Filtering facepiece	Delta N100	Yes
84A-0005	Tecnol, Inc.	1-800-832-6651	N95, Filtering facepiece	PFR 95 and Preventer 95	No
84A-0006	3M Company	1-800-243-4630	N95, Filtering facepiece	1860	No
84A-0007	3M Company	1-800-243-4630	N95, Filtering facepiece	8210 and 7048	No
84A-0008	Racal Health and Safety, Inc.	1-800-682-9500	N95, Filtering facepiece	Racal N95	No
84A-0009	Racal Health and Safety, Inc.	1-800-682-9500	R95, Filtering facepiece	Delta R95	Yes
84A-0010	Tecnol, Inc.	1-800-832-6651	N95, Filtering facepiece	PFR95 and Preventer95	No
84A-0011	Tecnol, Inc.	1-800-832-6651	N95, Filtering facepiece	PFR95 and Preventer95	No
84A-0012	Racal Health and Safety, Inc.	1-800-682-9500	N95, Filtering facepiece	Delta N95 + Odor	Yes
84A-0013	Moldex-Metric, Inc.	1-800-421-0668	N95, Filtering facepiece	2001 and 2002	No
84A-0014	Racal Health and Safety, Inc.	1-800-682-9500	N99, Filtering facepiece	Delta N99	No
84A-0015	Survivair	1-800-821-7236	N95, Filtering facepiece	1930	No
84A-0015	BioSafety Systems	1-800-421-6556	N95, Filtering facepiece	1930	No
84A-0016	Better Breathing, Inc.	1-800-638-6275	N95, Filtering facepiece	APR-7-N95-0	No
84A-0016	Uvex Safety	1-401-232-1200	N95, Filtering facepiece	Pro-Tech-N95	No
84A-0022	3M Company	1-800-243-4630	P100, Elastomeric half-mask	6000 Low-maintenance with 2091 filter	Yes
84A-0029	Uvex Safety	1-401-232-1200	N95, Filtering facepiece	Pro-Tech-N95-A	Yes
84A-0029	Better Breathing, Inc.	1-800-638-6275	N95, Filtering facepiece	APR-7-N95-1	Yes

84A-0030	3M Company	1-800-243-4630	P100, Elastomeric half-mask	7000 Series Conventional with 2091 filter	Yes
Approval Number	Supplier	Phone	Respirator Type	Trade Name	Exhalation Valve
84A-0031	3M Company	1-800-243-4630	P100, Elastomeric half-mask	7000 Series Bayonet Attachment with 2091 filter	Yes
84A-0038	3M Company	1-800-243-4630	P100, Elastomeric full face	7000 Series Conventional with 2091 filter	Yes
84A-0071	3M Company	1-800-243-4630	P100, Elastomeric half-mask	6000 Series Low Maintenance with 7093 filter	Yes
84A-0078	3M Company	1-800-243-4630	P100, Elastomeric half-mask	7000 Series Conventional with 7093 filter	Yes
84A-0079	3M Company	1-800-243-4630	P100, Elastomeric half-mask	7000 Series Bayonet Attachment with 7093 filter	Yes
84A-0086	3M Company	1-800-243-4630	P100, Elastomeric full face	7000 Series Conventional with 7093 filter	Yes
84A-0114	Moldex-Metric, Inc.	1-800-421-0668	N95, Filtering facepiece	8000 Series Half-mask with 8910 filters	Yes
84A-0115	Moldex-Metric, Inc.	1-800-421-0668	N99/R95 Filtering facepiece	8000 Series Half-mask with 8920 filters	Yes
84A-0116	Moldex-Metric, Inc.	1-800-421-0668	N100/P99	8000 Series Half-mask with 8930 filters	Yes
84A-0117	Moldex-Metric, Inc.	1-800-421-0668	P100	8000 Series Half-mask with 8940 filters	Yes
84A-0118	Mine Safety Appliances	1-800-672-2222	P100	Comfo-Series Half-mask with P100 or P100 Sparkfoe filters	Yes
84A-0119	Mine Safety Appliances	1-800-672-2222	P100	Comfo-Series Half-mask	Yes
84A-0120	Moldex-Metric, Inc.	1-800-421-0668	N95, Filtering facepiece	2071 and 2072 2051 and 2052 2061 and 2062	Yes
84A-0121	Mine Safety Appliances	1-800-672-2222	P100	Comfo-Series Half-mask with Comfo Low Profile filters	Yes
84A-0122	Mine Safety Appliances	1-800-672-2222	P100	Advantage 100 Half-mask with Comfo Low Profile filters or Advantage Low Profile filters	Yes

This table was last updated on 12/14/95.